

**Search results from the "OB\_Rx" table for query on "019516."**

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Active Ingredient: MORPHINE SULFATE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: MS CONTIN  
Applicant: PURDUE FREDERICK  
Strength: 30MG  
Application Number: 019516  
Product Number: 001  
Approval Date: May 29, 1987  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: MORPHINE SULFATE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: MS CONTIN  
Applicant: PURDUE FREDERICK  
Strength: 60MG  
Application Number: 019516  
Product Number: 002  
Approval Date: Apr 8, 1988  
Reference Listed Drug: Yes  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: MORPHINE SULFATE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: MS CONTIN  
Applicant: PURDUE FREDERICK  
Strength: 15MG  
Application Number: 019516  
Product Number: 003  
Approval Date: Sep 12, 1989  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: MORPHINE SULFATE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: MS CONTIN  
Applicant: PURDUE FREDERICK  
Strength: 100MG

Application Number: 019516  
Product Number: 004  
Approval Date: Jan 16, 1990  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: MORPHINE SULFATE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: MS CONTIN  
Applicant: PURDUE FREDERICK  
Strength: 200MG  
Application Number: 019516  
Product Number: 005  
Approval Date: Nov 8, 1993  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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**Search results from the "OB\_Rx" table for query on "020553."**

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Active Ingredient: OXYCODONE HYDROCHLORIDE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: OXYCONTIN  
Applicant: PURDUE PHARMA LP  
Strength: 10MG  
Application Number: 020553  
Product Number: 001  
Approval Date: Dec 12, 1995  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: OXYCODONE HYDROCHLORIDE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: OXYCONTIN  
Applicant: PURDUE PHARMA LP  
Strength: 20MG  
Application Number: 020553  
Product Number: 002  
Approval Date: Dec 12, 1995  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: OXYCODONE HYDROCHLORIDE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: OXYCONTIN  
Applicant: PURDUE PHARMA LP  
Strength: 40MG  
Application Number: 020553  
Product Number: 003  
Approval Date: Dec 12, 1995  
Reference Listed Drug: Yes  
RX/OTC/DISCN: RX  
TE Code: **AB**  
Patent and Exclusivity Info for this product: [View](#)

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Active Ingredient: OXYCODONE HYDROCHLORIDE  
Dosage Form;Route: TABLET, EXTENDED RELEASE; ORAL  
Proprietary Name: OXYCONTIN  
Applicant: PURDUE PHARMA LP  
Strength: 80MG

Application Number: 020553  
Product Number: 004  
Approval Date: Jan 6, 1997  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AB**  
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**Patent and Exclusivity Search Results from query on Appl No 020553 Product 001 in the OB\_Rx list.**

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**Patent Data**

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
<u>020553</u>	001	4861598	AUG 29,2006			
<u>020553</u>	001	4970075	AUG 29,2006			
<u>020553</u>	001	5266331	OCT 26,2007		Y	
<u>020553</u>	001	5508042	APR 16,2013			<u>U-443</u>
<u>020553</u>	001	5549912	OCT 26,2007		Y	
<u>020553</u>	001	5656295	OCT 26,2007			<u>U-443</u>

**Exclusivity Data**

**There is no unexpired exclusivity for this product.**

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Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
4. \*PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with \*PED as was done prior to August 18, 2003. Patents with \*PED added after August 18, 2003 will not contain any information relative to the patent itself other than the \*PED extension. Information related specifically to the patent will be conveyed on the original patent only.
5. U.S. Patent Nos. RE 36481 and RE 36520 were relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v. Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents remained listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

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